In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-1512V

PUBLISHED

TERRY PITTS,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

Filed: March 10, 2023

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Shoulder Injury Related to Vaccine Administration ("SIRVA"); Table Injury; Cause-in-fact; Influenza ("flu") vaccine; Denial; Onset

Terry Pitts, Evanston, IL, pro se petitioner.
Camille Michelle Collett, U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

On September 28, 2018, petitioner, Terry Pitts, filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10-34 (2012),[2] alleging that he suffered "injuries, including Shoulder Injury Related to Vaccine Administration ("SIRVA")" resulting from adverse effects of his October 8, 2016 influenza ("flu") vaccination. (ECF No. 1.) For the reasons set forth below, I conclude that petitioner is not entitled to compensation. The key issue is the timing of onset of petitioner's alleged post-vaccination shoulder injury.

[1] Because this document contains a reasoned explanation for the special master's action in this case, it will be posted on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. *See* 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the document will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information the disclosure of which would constitute an unwarranted invasion of privacy. If the special master, upon review, agrees that the identified material fits within this definition, it will be redacted from public access.

[2] Within this decision, all citations to § 300aa will be the relevant sections of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a causal link between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300 aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

As relevant here, the Vaccine Injury Table lists a Shoulder Injury Related to Vaccine Administration or "SIRVA" as a compensable injury if it occurs within 48 hours of administration of a vaccination. § 300aa-14(a) as amended by 42 CFR § 100.3. Table Injury cases are guided by statutory "Qualifications and aids in interpretation" ("QAIs"), which provide more detailed explanation of what should be considered when determining whether a petitioner has actually suffered an injury listed on the Vaccine Injury Table. 42 CFR § 100.3(c). To be considered a "Table SIRVA," petitioner must show that his injury fits within the following definition:

> SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis . . . . A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time-frame;

> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 CFR § 100.3(c)(10).

Alternatively, if no injury falling within the Table can be shown, the petitioner may still demonstrate entitlement to an award by showing that the vaccine recipient's injury or death was caused-in-fact by the vaccination in question. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(ii). To so demonstrate, a petitioner must show that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). In particular, a petitioner must show by preponderant evidence: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury in order to prove causation-in-fact. *Althen v. Sec'y of Health & Human Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005).

For both Table and Non–Table claims, Vaccine Program petitioners must establish their claim by a "preponderance of the evidence". § 300aa-13(a). That is, a petitioner must present evidence sufficient to show "that the existence of a fact is more probable than its nonexistence . . . ." *Moberly*, 592 F.3d at 1322 n.2. Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). However, a petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1). Once a petitioner has established their *prima facie* case, the burden then shifts to respondent to prove, also by preponderant evidence, that the alleged injury was caused by a factor unrelated to vaccination. *Althen,* 418 F.3d at 1278 (citations omitted); § 300aa-13(a)(1)(B).

In this case, petitioner stresses that he suffered a left-sided shoulder injury consistent with a SIRVA Table Injury. (ECF No. 43, p. 1.) Alternatively, petitioner asserts that reliable medical evidence supports a non-Table shoulder injury caused-in-fact by his vaccination. (*Id.* at 6.)

II. Procedural History

At the time the case was filed, petitioner was represented by counsel. He did not become a *pro se* petitioner until January 25, 2023. (ECF No. 55.) This case was initially assigned to the Special Processing Unit ("SPU") for expedited resolution based on the allegations of the petition. (ECF No. 5.) Over several months, petitioner filed evidence, including medical records, affidavits, and a letter by a treating physician,

marked as Exhibits 1-9. (ECF Nos. 7, 9, 11.) Respondent then advised as of August 5, 2019, that he intended to defend the case and later filed his Rule 4(c) Report setting forth his view of the case on October 4, 2019. (ECF Nos. 17, 20.) Respondent primarily raised the issue that petitioner's medical records did not support a timing of onset compatible with a Table injury of SIRVA. He additionally raised that without an expert report the medical records were inadequate to support a cause-in-fact shoulder injury claim. (ECF No. 20, pp. 6-9.)

Subsequently, the Chief Special Master issued an order advising that "I intend to issue a fact finding as to the onset of petitioner's alleged injury after providing the parties an opportunity to file any further evidence they wish to have considered. Because this ruling relates to a discrete factual issue, party briefs are not necessary." (ECF No. 21.) However, the Chief Special Master allowed the parties time to file either additional evidence and/or memoranda regarding onset. (*Id*.) Petitioner subsequently filed a Statement of Completion without filing any additional evidence and neither party filed any brief. The Chief Special Master issued his finding of fact on April 29, 2020. (ECF No. 25.) The Chief Special Master concluded there is evidence to support onset occurring one week post-vaccination, but not preponderant evidence of onset occurring within 48-hours of vaccination. (*Id*. at 8.)

Following the finding of fact, petitioner filed an amended petition to explicitly assert an alternative claim based in causation-in-fact (ECF No. 29), along with an expert report by orthopedist Uma Srikumaran, M.D. (ECF No. 28; Exs. 10-17.) At that point, the Chief Special Master removed the case from the SPU and it was reassigned to Special Master Roth. (ECF Nos. 30-31.) Respondent advised that he would continue to defend the case (ECF No. 35) and he filed a responsive expert report by orthopedist Paul Cagle, M.D., on February 3, 2021 (ECF No. 36; Ex. A-B). Petitioner then filed a further report by Dr. Srikumaran responding to Dr. Cagle's report. (ECF No. 37; Exs. 18-24.) Respondent was provided an opportunity to file a further expert report but declined. (ECF No. 38.)

Initially, petitioner requested a hearing (ECF No. 39); however, petitioner subsequently filed a joint status report on behalf of the parties opting instead to proceed to a ruling on the existing record without a hearing (ECF No. 40). Petitioner filed his motion for a ruling on the record on July 30, 2021. (ECF No. 43.) Respondent filed a response on September 28, 2021. (ECF No. 46.) Petitioner filed his reply on October 5, 2021. (ECF No. 47.) In his motion, petitioner argued both that his claim can prevail based on a one-week onset under a causation-in-fact theory and that the Chief Special Master's prior fact finding should be revisited by the presiding special master such that a Table SIRVA claim may still be viable. (ECF No. 43.)

Subsequently, however, on May 2, 2022, petitioner's counsel filed a motion for an award of interim attorneys' fees and costs as well as a motion to withdraw as attorney of record. (ECF Nos. 49-50.) In the motion to withdraw, petitioner's counsel represented that "petitioner and his counsel have developed irreconcilable differences as to how to best advance the prosecution of his petition." (ECF No. 50, p. 1.) Special

Master Roth granted counsel's motion to withdraw on January 25, 2023, and petitioner became a *pro se* petitioner.[3] (ECF No. 55.)

Shortly thereafter, this case was reassigned to the undersigned on February 2, 2023. (ECF Nos. 58-59.) On February 3, 2023, I issued a scheduling order setting forth the procedural history of the case and explaining the case has "since been reassigned to the undersigned and I intend to resolve the case expeditiously. However, although the case has already been briefed for a ruling on the existing record, petitioner's counsel's withdrawal based on irreconcilable differences with petitioner raises a question as to whether the case remains ripe for resolution." (ECF No. 62, pp. 1-2.) I advised the parties that I intend to rule on petitioner's pending motion for a ruling on the record as soon as practicable, but afforded the parties a period of two weeks to notify me of any objection to my acting on the pending motion. (*Id*. at 2.) No objection was raised by either party.

I have determined that the parties have had a full and fair opportunity to present their cases and that it is appropriate to resolve this issue without a hearing. *See* Vaccine Rule 8(d); Vaccine Rule 3(b)(2); *Kreizenbeck v. Sec'y of Health & Human Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020) (noting that "special masters must determine that the record is comprehensive and fully developed before ruling on the record."). Accordingly, this matter is now ripe for resolution.

III. Factual History

Petitioner was 42 years old at the time of the vaccination at issue. There is no indication that he had any prior contributory medical history. (ECF No. 46, p. 2 (citing Ex. 1, p. 1; Ex. 2, pp. 25-26; Ex. 3, pp. 18-19).) Petitioner presented to his primary care physician, Kyong Christopher Oh, M.D., on October 8, 2016, for a general adult exam and, it appears, to establish care.[4] He received the flu vaccination at issue at this encounter. It was administered in his left deltoid. (Ex. 1; Ex. 3, p. 19.) Petitioner was directed to follow up in four weeks regarding his prescriptions. (Ex. 3, pp. 18-19.)

In his affidavit, petitioner states that he experienced immediate upper arm pain after being vaccinated. (Ex. 7, p. 1.) He indicates he called Dr. Oh's office later that day to complain of his ongoing pain. (*Id.*) He also indicates that during the same call he requested that an unrelated prescription be sent to Sam's Club Pharmacy. (*Id.*) Dr. Oh's medical records do not include any record of a call from petitioner, though the body of records does otherwise have telephone encounter records. There is a record of a call from Sam's Club Pharmacy on October 14, 2016, indicating that they had not received necessary prescriptions. (Ex. 3, p. 17.) Petitioner's wife also signed an affidavit stating that she recalled discussing petitioner's arm pain with him as of the morning after the vaccination. (Ex. 6.) She states that the pain began the day of the vaccination. (*Id.*)

[3] Former counsel's motion for an award of attorneys' fees and costs remains pending.
[4] The record indicates petitioner had recently moved to the area from Alabama. (Ex. 3, p. 18.)

Petitioner's medical records suggest that he returned to Dr. Oh approximately one month later. However, the records present a confusing picture of when exactly that follow up occurred, because the records purport to show that he followed up on both November 5, 2016, and November 7, 2016, which is highly unlikely. Based on the record as a whole, it appears most likely that petitioner had only one check up with Dr. Oh in early November of 2016, most likely on November 7. A medical record of November 7, 2016, indicates petitioner is "[d]oing well here for checkup – medications going well without side effect . . . Due for Rx today." (Ex. 3, p. 13.) This is consistent with what his prior October 8 record suggested was the purpose of his follow up. The encounter record for November 5, 2016, indicates more vaguely that the reason for appointment was "1 month f/u." (*Id.* at 15-16.) That record is also identified as a checkup. (*Id.*) The November 5 record contains no instruction for petitioner to follow up again in two days and the November 7 record includes no notation to suggest petitioner had been seen just two days prior. (*Id.* at 13-16.) Nothing in either medical record otherwise indicates any reason why petitioner would be seen twice in the span of two days for a routine follow up regarding his ongoing medications. Whereas the record of the November 7, 2016, encounter has an electronic signature by Dr. Oh matching the date of the encounter (*Id.* at 14), Dr. Oh's electronic signature on the November 5, 2016, encounter record is dated March 14, 2018 (*Id.* at 15). Both records confirm petitioner should continue his medications; however, there is more detailed discussion regarding petitioner's conversations with Dr. Oh in the November 7 record. (*Compare,* Ex. 3, p. 13 *and*, *id.* at 15.) In any event, both records include the same physical examination and review of systems notations, though only the November 7 encounter recorded petitioner's vital signs. (Ex. 3, pp. 13, 15.) Physical exam of the extremities was limited to noting no edema. The review of systems for musculoskeletal is limited to noting "joint pain denies" in both records. (*Id.* at 13, 16.)

There is no indication within either record that petitioner's shoulder was discussed. Petitioner's affidavit indicates, however, that he discussed his shoulder pain with Dr. Oh at the November 7 encounter. (Ex. 7, p. 1). Additionally, two later letters by Dr. Oh have been filed in this case. (Exs. 5, 9.) The first letter dated October 4, 2018, indicates that Dr. Oh does recall that on November 7, 2016, petitioner reported to him that he had been having left shoulder pains. (Ex. 5.) In a later letter dated January 24, 2019, Dr. Oh clarifies that "[d]uring an appointment in early November 2016, [petitioner] mentioned to me that he was having shoulder pain that began immediately after he received his flu vaccine on 10/08/2016." (Ex. 9.) Neither Dr. Oh nor petitioner ever reference an appointment occurring November 5, 2016. (Exs. 5, 7, 9.)

Petitioner did not seek care again until February 21, 2017. (Ex. 3, pp. 10-11.) A telephone record of February 20, 2017, suggests that the appointment was prompted by the need to renew one of his prescriptions, which as a controlled substance required a follow up appointment; however, when petitioner presented the next day the history of present illness indicated that he complained of "some pains in the left arm," further noting that "he does total gym but is finding it difficult to do much exercise." (*Compare* Ex. 3, p. 10 *and, id.* at 12.) Despite presenting with a complaint of shoulder pain, petitioner's documented physical exam was still limited to noting that he had no edema

in his extremities and his review of systems still recorded "joint pain denies" under musculoskeletal. (Ex. 3, p. 10.) Petitioner was assessed with "left shoulder pain" and referred to an orthopedist. (*Id.* at 10-11.)

Petitioner then saw orthopedist Steven Levin, M.D., the next day. (Ex. 4, p. 8.) At that time he provided a history "complaining of left shoulder pain for 4 months after he got a flu shot in October. He said it specifically started after he got a flu shot." (*Id.*) Petitioner complained of "discomfort in and around the biceps area and into the shoulder, pain with overhead activity, pain at night." (*Id.*) Additionally, "he had some instances of mild numbness and tingling, but that since dissipated, no weakness in the arm." (*Id.*) Physical exam indicated his neck was non-tender and with full range of motion. (*Id.* at 9.) Spurling's and Lhermitte's tests were both negative.[5] Physical exam of the shoulder indicated "basically full painless range of motion" with mild pain at the extremes of forward flexion along with "mildly positive" Neer and Hawkins tests.[6] (*Id.*) Several additional tests were negative. (Ex. 4, p. 9.) X-rays were negative. (*Id.*) Dr. Levin's impression was bursitis. (*Id.*) He further indicated that he has had prior patients he believed to have had inflammatory bursitis due to flu vaccinations penetrating the bursa. (*Id.*) He then added "that is my diagnosis at this juncture in time." (*Id.*) Dr. Levin recommended conservative treatment, including physical therapy. (*Id.*)

Petitioner subsequently presented for a physical therapy evaluation on March 14, 2017. (Ex. 4, pp. 71-74.) At that time he reported that he "[r]ecieved flu shot in fall 2016 and about 1 week later noticed soreness in L lateral arm . . . Progressively has been worsening and increased area of pain." (*Id.* at 71.) The pain was characterized as intermittent and sharp, 7/10 at worst, and aggravated by several activities involving the lifting of the arm as well as working out. The pain was described as lateral shoulder

[5] A Spurling test tests for the presence of cervical radiculopathy where "the examiner presses down on the top of the head while the patient rotates the head laterally and into hyperextension; pain radiating into the upper limb ipsilateral to a rotation position of the head indicates radiculopathy." *Spurling test,* DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=112983&searchterm=Spurling%20test (last accessed Mar. 1, 2023). The Lhermitte sign is "the development of sudden, transient, electric-like shocks spreading down the body when the patient flexes the head forward; seen mainly in multiple sclerosis but also in compression and other disorders of the cervical cord." *Lhermitte sign,* DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=106344&searchterm=Lhermitte%20sign (last accessed Mar. 1, 2023).

[6] A Hawkins-Kennedy test is a test used in the evaluation of orthopedic shoulder injury. "A positive Hawkins-Kennedy test is indicative of an impingement of all structures that are located between the greater tubercle of the humerus and the coracohumeral ligament." *Hawkins-Kennedy test,* WIKIPEDIA, https://en.wikipedia.org/wiki/Hawkins%E2%80%93Kennedy_test (last accessed Mar. 1, 2023). A Neer impingement test is a test designed to reproduce symptoms of rotator cuff impingement "through flexing the shoulder and pressure application." *Neer Impingement Test,* WIKIPEDIA, https://en.wikipedia.org/wiki/Neer_Impingement_Test (last accessed Mar. 1, 2023). In a Neer's test, symptoms should be reproduced "if there is a problem with the supraspinatus or biceps brachii." *Id.*

pain initially that spread to the top of the shoulder and into axilla.[7] Petitioner reported that he had been able to use 50-pound dumbbells on his Total Gym system, but was currently unable to use that system for working out. (*Id.*) The objective assessment showed normal cervical range of motion without exacerbation when tested, although petitioner reported left side tightness with some maneuvers. (*Id*. at 72.) Petitioner had reduced range of shoulder movement and his Hawkins test was positive. (*Id*.) Six weeks of physical therapy was recommended. (*Id*. at 73.)

Petitioner attended five further physical therapy sessions during March of 2017. (Ex. 4, pp. 75-85.) During that time, petitioner reached out to Dr. Oh by telephone on March 22, 2017, to discuss his shoulder pain. (Ex. 3, p. 9.) He indicated that he was still having pain despite his therapy. (*Id*. at 8.) Dr. Oh sent a message to Dr. Levin recommending that petitioner follow up with him for further recommendation. Dr. Oh included an addendum in his record that "I also made it clear to patient that his shoulder pain is not the result of the flu shot he received on 10/8/16." (*Id*.) Subsequently, on March 30, 2017, petitioner's physical therapist likewise concluded that petitioner had made no significant progress and that the referring physician should reevaluate the need for further physical therapy. (Ex. 4, pp. 84-85.)

Petitioner returned to Dr. Levin on April 3, 2017. (Ex. 4, p. 25.) In addition to findings relative to his shoulder, Dr. Levin also observed that:

> he has numbness and tingling going down his arm as well as radicular type pain. This all started after a flu injection. He may have developed some adhesive capsulitis due to protecting his shoulder from the pain of a flu shot and/or he might have developed some radiculopathy, it is difficult to discern.

(*Id*.) Dr. Levin recommended an EMG as well as an MRI of both the neck and shoulder. (*Id*. at 26.)

An EMG/NCV study was conducted on April 6, 2017, to rule out cervical radiculopathy, plexopathy, and/or carpal tunnel syndrome. (Ex. 4, pp. 21-23.) The study was interpreted as "essentially normal." (*Id*. at 22.) The cervical spinal MRI was conducted on April 13, 2017. It found disc protrusion at C5-C6, but without evidence of extrinsic compression of the cervical spinal cord. (*Id*. at 24.) Petitioner's left shoulder MRI of the same date showed no rotator cuff or labral tear, but edema around the glenohumeral ligament and rotator cuff interval consistent with adhesive capsulitis. (*Id*. at 20.) Petitioner returned to Dr. Levin on April 17, 2017, to review his results. (*Id.* at 33-34.) Based on his review of the test results, Dr. Levin recommended that petitioner

[7] "[T]he pyramidal region of the upper limb between the upper thoracic wall and the shoulder, its base formed by the skin and apex bounded by the approximation of the clavicle, coracoid process, and first rib[.]" *Axilla,* DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=5152&searchterm=axilla (last accessed Mar. 1, 2023).

follow up with a cervical spine specialist, but also recommended a steroid injection for his shoulder and that he continue "aggressive" therapy for adhesive capsulitis.[8] (*Id.*)

Petitioner had one further encounter with Dr. Oh on May 20, 2017, before establishing care with a new primary care provider, Emily Andrew, M.D., on July 15, 2017. (Ex. 3, pp. 5-6; Ex. 4, p. 41-42.) The May 20th encounter with Dr. Oh was a three-month checkup. The record documents petitioner's left shoulder pain in the assessments but is otherwise uninformative. (Ex. 3, p. 5.) (As with the November 5, 2016 encounter, this record is electronically signed as of March 14, 2018.) When petitioner presented to Dr. Andrew, the fact of his ongoing orthopedic treatment for left shoulder pain was documented, but the appointment appears to have focused more heavily on his diabetes management. (Ex. 4, pp. 41-42.) Petitioner declined a physical therapy referral. (*Id.* at 42.)

On August 31, 2017, petitioner underwent an employment related health screening. (Ex. 8.) He completed a questionnaire that marked "no" for any prior neck or back problems and "no" for any "[b]one, muscle, joint, or nerve problems." (*Id.* at 3.) A physical examination checked "normal." (*Id.* at 4.) However, the extent of the physical exam is not indicated. (*Id.*) No further records were filed. Both petitioner and his wife indicate in their affidavits, both signed in December of 2018, that petitioner has experienced ongoing symptoms up to that point. (Ex. 7, p. 2 ("[t]hroughout this whole ordeal I have been in tremendous pain . . . ."); Ex. 6, p. 1 ("[t]o this day, [petitioner] has yet to fully recover from receiving the vaccine").

IV. Expert Reports

a. Petitioner's Initial Expert Report by Orthopedist Uma Srikumaran, M.D., MBA, MPH[9]

[8] The same day petitioner once again contacted Dr. Oh's office by phone and requested information regarding the vaccine had head received on October 8, 2016. (Ex. 3, p. 7.) The office reportedly told petitioner that his vaccination had been administered correctly and "had nothing to do" with his shoulder pain. (*Id.*)

[9] Dr. Srikumaran serves as an associate professor in the Shoulder Division at the Johns Hopkins School of Medicine and serves as the Shoulder Fellowship Director and Chair of Orthopaedic Surgery for the Howard County General Hospital. (Ex. 10, p. 1.) He also serves as the Medical Director of the Johns Hopkins Musculoskeletal Service Line in Columbia, Maryland. (*Id.*) Each year Dr. Srikumaran sees approximately 2500-3000 patients for shoulder issues and performs 400-500 shoulder surgeries annually. (*Id.*) He has treated approximately ten to twelve patients with shoulder dysfunction after vaccination in the past five years. (*Id.*) Dr. Srkumaran received his medical degree from Johns Hopkins School of Medicine in 2005. (Ex. 11, p. 1.) He completed his orthopaedic residency at Johns Hopkins Hospital and completed a shoulder surgery fellowship at Massachusetts General Hospital. (*Id.*) Dr. Srikumaran is board certified in orthopaedic surgery. (*Id.* at 10.) He peer reviews journal articles for several orthopaedic journals including The Journal of Bone & Joint Surgery, Orthopedics, Clinical Orthopedics and Related Research, and The Journal of Shoulder and Elbow Surgery. (Ex. 10, pp. 1-2.) Dr. Srikumaran was selected to serve on the Shoulder and Elbow Content Committee for the American Academy of Orthopaedic Surgery. (*Id.*)

Dr. Srikumaran indicates that there is scientific literature available to demonstrate that "injection of a vaccine antigen into the subacromial bursa [can lead] to a 'robust local immune and inflammatory response' leading to pathology of the subacromial space, biceps tendon, glenohumeral joint, and capsulitis." (Ex. 10, p. 5 (citing Marko Bodor & Enoch Montalvo, *Vaccination-related shoulder dysfunction,* 25 VACCINE 585 (2007) (Ex. 14); S. Atanasoff et al., *Shoulder injury related to vaccine administration (SIRVA),* 28 VACCINE 8049 (2010) (Ex. 12)).) Further to this he cites experimental evidence that he indicates shows the plausibility of inflammation caused by immune mediated response to antigenic material. (*Id.* (citing D.C. Dumonde & L.E. Glynn, *The production of arthritis in rabbits by an immunological reaction to fibrin,* 43(4) BRIT. J. EXP. PATHOL. 373 (1962) (Ex. 15); C. Trollmo et al., *Intra-articular immunization induces strong systemic immune response in humans,* 82 CLIN. EXP. IMMUNOL. 384 (1990) (Ex. 17)).) In that regard, Dr. Srikumaran stresses that petitioner "consistently and reliably" reported post-vaccination shoulder pain to his treating physicians culminating in a diagnosis of bursitis. (*Id*. at 6-7.) To the extent petitioner was later diagnosed with adhesive capsulitis after failing physical therapy, he further opines that adhesive capsulitis is also consistent with SIRVA. (*Id*. at 7.) Dr. Srikumaran feels confident that cervical radiculopathy was ruled out by the treating physicians after a normal EMG/NCS and that there are no reports to suggest that petitioner had any history of other shoulder conditions that would explain his symptoms. (Ex. 10, pp. 6-7.) Noting that petitioner reported onset of his shoulder pain occurring within one week of vaccination, he opines that this is appropriate timing. (*Id*.) Dr. Srikumaran cites a review paper that he indicates provides support for a latency for SIRVA-like shoulder injuries of up to two months post-vaccination. (*Id*. at 5 (citing L.H. Martin Arias, *Risk of bursitis and other injuries and dysfunctions of the shoulder following vaccinations,* 35 VACCINE 4870 (2017) (Ex. 13)).)

b. Respondent's Expert Report by Orthopedist Paul J. Cagle, M.D.[10]

Dr. Cagle stresses that when petitioner first sought care from Dr. Levin on April 3, 2017, he presented with a mixed picture of "signs of bursitis as well as signs of radicular pain." (Ex. A, p. 4.) He noted that Dr. Levin felt the clinical picture was unclear, recommending both further evaluation of the cervical spine and a steroid injection to the shoulder. (*Id*.) Further to this, Dr. Cagle does not view petitioner's shoulder MRI results

[10] Dr. Cagle serves an as assistant professor and Associate Program Director in the Department of Orthopaedic Surgery at the Icahn School of Medicine at Mount Sinai. (Ex. A, p. 1.) He is a member of the American Shoulder and Elbow Surgeons, and a faculty member of an internationally recognized shoulder surgery fellowship. (*Id.*) His current practice focuses on the shoulder, representing 95% or more of the patients and pathology he treats. (*Id.*) Dr. Cagle conducts clinical, biomechanical, and basic science research. (*Id.*) He has presented scientific work nationally and internationally; and has published over twenty articles related to shoulder injuries and surgery. (Ex. B, pp. 11-12.) Dr. Cagle is a peer reviewer for the Journal of Orthopaedic Research, Techniques in Shoulder and Elbow Surgery, and the Journal of Shoulder and Elbow Surgery. (*Id.* at 13.) He received his medical degree from Loyola University Chicago Stritch School of Medicine in 2008. (*Id.* at 2.) Dr. Cagle completed his orthopaedic residency at the University of Minnesota Academic Health center and Medical School. (*Id.*) He also completed a shoulder and elbow fellowship at Mount Sinai Hospital in New York and is board certified in orthopaedic surgery. (*Id.*)

as supporting SIRVA because they do not show an increase in bursal fluid. (*Id*.) Moreover, Dr. Cagle indicates that the MRI results and physical exam are in contrast regarding the shoulder pathology at issue. He suggests that the MRI shows inflammation of the inferior glenohumeral ligament, which is consistent with adhesive capsulitis, while the physical exam of February 22, 2017, demonstrated no loss of motion, which is incompatible with adhesive capsulitis. (*Id*.) In contrast, he stresses that the cervical spine MRI showed protrusion of the neural foramen of the left C5-6 nerve. Thus, Dr. Cagle appears to suggest that it is the cervical spine MRI rather than the shoulder MRI that evidences an acute explanation for petitioner's condition. Dr. Cagle charges that Dr. Srikumaran's explanation of the MRI findings is selective. (*Id.* at 4-5.) Dr. Cagle contends that the literature cited by Dr. Srikumaran is inapposite due to the lack of evidence of a shoulder-based etiology for petitioner's condition and also that the literature is unpersuasive in itself because it does not establish a mechanism to support the association it seeks to present between vaccination and shoulder dysfunction. (*Id*. at 5-6.)

c. Petitioner's Supplemental Expert Report by Dr. Srikumaran

In response to Dr. Cagle's assessment of the clinical history, Dr. Srikumaran stresses that the April 3, 2017, encounter discussed by Dr. Cagle was not Dr. Levin's first examination of petitioner and that on February 22, 2017, Dr. Levin opined after physical examination that petitioner had bursitis that he attributed to the vaccination. (Ex. 18, p. 1.) Dr. Srikumaran agrees that cervical radiculopathy was within the differential diagnosis, but disagrees regarding Dr. Cagle's assessment that the cervical etiology is more likely. He stresses that the April 3, 2017, physical examination demonstrated reduced range of motion, crepitus, and positive Neer and Hawkins tests. These are consistent with shoulder pathology whereas the same exam shoed a non-tender neck exam with full range of motion and a negative Spurling's test, all of which are inconsistent with cervical radiculopathy. (*Id.* at 2.) Dr. Srikumaran notes that Dr. Levin was concerned regarding radicular pain as well as numbness and tingling down the arm but suggests that radiating pain is not incompatible with SIRVA or adhesive capsulitis. (*Id.*) Dr. Srikumaran again stresses that petitioner's shoulder MRI was consistent with adhesive capsulitis and disagrees that the February 22, 2017, physical exam is in conflict with that finding, suggesting the "mild pain on extremes of forward flexion" is consistent with early signs of adhesive capsulitis while more advanced signs of adhesive capsulitis are documented in later records. (*Id*.) Dr. Srikumaran also provided an expanded discussion of his opinion with regard to general causation, adding citations to a number of additional publications. (*Id*. at 3-7.) Among those additional citations, Dr. Srikumaran added a discussion of a study by Hesse, et al., that demonstrates a statistically significant risk of bursitis following vaccination. (*Id*. at 6 (citing Elisabeth Hesse et al., *Risk for subdeltoid bursitis after influenza vaccination,* 173 ANN. INTERN. MED. 253 (2020) (Ex. 21).)

V. Discussion

a. Timing of Onset

As a threshold matter, petitioner has specifically requested in his motion that the presiding special master revisit the Chief Special Master's finding of fact regarding onset. (ECF No. 43, p. 3 (requesting that the currently presiding special master independently evaluate onset).) Respondent offered no competing argument in his motion response. Although I ultimately have reached the same result as the Chief Special Master, revisiting the basis for my finding of fact in the interest of completeness is advisable for three reasons.

First, the fact finding of a previously assigned special master is not binding upon a subsequently presiding special master. *Godfrey v. Sec'y of Health & Human Servs.*, 2015 WL 10710961, at *9 (Fed. Cl. Spec. Mstr. Oct. 27, 2015) (noting that "[g]enerally, special masters may change or revisit any ruling until judgment enters, even if the case has been transferred."); *see also Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed.Cl. 625, 630 (1998), *aff'd*, 191 F.3d 1344 (Fed. Cir. 1999) (special masters are not bound by their own or other special masters' decisions). Second, petitioner correctly notes that subsequent Federal Circuit authority at least raises a question as to elements of the Chief Special Master's analysis. (ECF No. 43, p. 4.) In particular, the Chief Special Master cited *Sanchez v. Secretary of Health and Human Services*, for the proposition that a series of three linked propositions regarding the manner in which people seek healthcare favors a presumption in favor of contemporaneous medical records. (ECF No. 25 (citing 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013), *vacated on other grounds*, *Sanchez by & through Sanchez v. Sec'y of Health & Human Servs.*, 809 Fed.Appx. 843 (Fed. Cir. 2020).) Subsequent to the issuance of this fact finding, however, the Federal Circuit in *Kirby v. Secretary of Health & Human Services*, specifically rejected these propositions as a misreading of prior precedent.[11] 997 F.3d 1378, 1383 (Fed. Cir. 2021). And, third, based on my evaluation of the record as a whole, I do not necessarily agree that petitioner sought care twice in November of 2016, a point that partly underlies the fact finding.

As petitioner suggests in his motion, the Federal Circuit has observed that "[a]lthough a patient has a 'strong motivation to be truthful' when speaking to his physician, that does not mean he will report every ailment he is experiencing, or that the physician will accurately record everything he observes." *Kirby*, 997 F.3d at 1383. Furthermore, it has also previously been observed that "[m]edical records are only as accurate as the person providing the information." *Parcells v. Sec'y of Health & Human Servs.*, No. 03-1192V, 2006 WL 2252749, at *2 (Fed. Cl. Spec. Mstr. July 18, 2006). And, importantly, "the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or

[11] In *Kirby* the Federal Circuit discussed a different decision, *Robi versus Secretary of Health & Human Services*, that relied on the same series of propositions in evaluating contemporaneous medical records. As the Federal Circuit discussed it in *Kirby*, the *Robi* decision concluded that these propositions supported a presumption that contemporaneous medical records are both complete and accurate. *Kirby,* 997 F.3d at 1382-83. It is that presumption that the Federal Circuit ultimately rejected as going beyond the prior suggestion in *Curcuras* that contemporaneous medical records can carry significant weight. *Id*. Here, the Chief Special Master did not explicitly rely on a presumption that the contemporaneous medical records were complete.

circumstance." *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl.Ct. 726, 733 (1991) (quoting the decision below), *aff'd per curiam,* 968 F.2d 1226 (Fed. Cir. 1992). The *Murphy* Court also observed that "[i]f a record was prepared by a disinterested person who later acknowledged that the entry was incorrect in some respect, the later correction must be taken into account." *Murphy*, 23 Cl.Ct. at 733.

I perhaps find less significance than did the Chief Special Master in the fact that petitioner's complaint of shoulder pain was not documented during his treatment with Dr. Oh in November of 2016. (*See* Ex. 3, pp. 13-16.) For the reasons discussed in the factual history above, I conclude it is more likely that the medical records reflect only one encounter at that time, rather than the two encounters discussed in the Chief Special Master's fact finding. Thus, this was not likely a repeated omission. Moreover, Dr. Oh has indicated, albeit much more remotely, that his original record was not complete with respect to petitioner's complaint of shoulder pain. (Exs. 5, 9.) Although the November encounter records also purported to indicate in a review of systems that petitioner denied any musculoskeletal complaints, this same notation was also included in Dr. Oh's February 21, 2017, record wherein petitioner specifically presented with a complaint of left shoulder pain. (*Compare* Ex. 3, p. 10 *with,* Ex. 3, p. 13 *and*, Ex. 3, p. 16.) Thus, I am not persuaded it is a reliable notation. Accordingly, I do not consider Dr. Oh's November 2016 body of medical records to be strong evidence regarding whether petitioner was experiencing shoulder pain at that time.

Significantly, however, the one time during his course of treatment when the onset of petitioner's shoulder pain was reported with specificity, petitioner told his physical therapist on March 14, 2017, that he experienced pain "about 1 week" after his vaccination. (Ex. 4, p. 71.) Petitioner also associated his pain to his vaccination on other occasions, but none of these records include enough specificity to contradict his specific report of pain beginning one-week post-vaccination. (Ex. 4, p. 8 (noting onset four months prior and "after" flu vaccine); Ex. 4, p. 41 ("started after flu injection."). Nor is there any contemporaneous record to support petitioner's recollection that he called Dr. Oh's office the day of his vaccination despite the fact that Dr. Oh's office otherwise regularly created records of his calls. Although Dr. Oh's later letter provides some evidence to suggest petitioner reported the onset of his pain as occurring "immediately" after his vaccination (Ex. 9), the March 14, 2017, history provided to the physical therapist remains the earliest recollection in evidence on this record regarding the specific onset of petitioner's shoulder pain. When a treating physician offers a statement that is not contemporaneous to events and is not within the context of diagnosis and treatment, a special master may conclude that it is not entitled to the same weight as contemporaneous medical records. *See Milik v. Sec'y of Health & Human Servs.*, 822 F.3d 1367, 1381-82 (Fed. Cir. 2016).

Based on my own independent review of the complete record, I conclude that there is not preponderant evidence that onset of petitioner's shoulder pain began within 48-hours of vaccination. Further to this finding, I also conclude that the evidence preponderates in favor of onset occurring within one-week post-vaccination.

b. Table SIRVA

As explained above, there is not preponderant evidence that onset of petitioner's alleged shoulder injury occurred within 48 hours of his vaccination. This defeats petitioner's Table injury claim for the reasons discussed in Section I, above. *See* 42 CFR § 100.3(c)(10)(ii).

c. Causation-in-fact

For the reasons discussed below, the one-week post-vaccination onset in this case is singularly fatal to petitioner's claim on this record. As discussed under *Althen* prong one below, petitioner is persuasive in establishing that the flu vaccine can in general cause shoulder injuries of the type reflected in his medical records and, as discussed under *Althen* prong two, Dr. Levin and Dr. Srikumaran demonstrate that petitioner likely did suffer shoulder pathology in addition to his suspected cervical spinal degeneration. However, as discussed under *Althen* prong three, Dr. Srikumaran is unpersuasive on this record in seeking to extend the necessary causal inference as far out as a full week post-vaccination.

i. *Althen* prong one

Petitioner is required to present a persuasive medical theory of causation demonstrating that the influenza vaccine could have caused his shoulder condition. *Althen,* 418 F.3d at 1278. It is well-established in the Vaccine Program that compensation may be awarded for shoulder injuries on a cause-in-fact basis. *See, e.g.*, *A.P. v. Sec'y of Health & Human Servs.,* No. 17-784V, 2022 WL 275785 (Fed. Cl. Spec. Mstr. Jan. 31, 2022); *L.J. v. Sec'y of Health & Human Servs.,* No. 17-0059V, 2021 WL 6845593 (Fed. Cl. Spec. Mstr. Dec. 2, 2021); *Tenneson v. Sec'y of Health & Human Servs*., No. 16-1664V, 2018 WL 3083140 (Fed. Cl. Spec. Mstr. Mar. 30, 2018), *rev. den.*, 142 Fed. Cl. 329 (2019). However, petitioner's medical theory must be supported by "reputable" scientific evidence and must "pertain[] specifically to the petitioner's case." *Moberly,* 592 F.3d at 1322.

Petitioner may not merely rely on the fact that SIRVA was added to the Vaccine Injury Table to establish a medical theory for a cause-in-fact claim. *Grant v. Sec'y of Health & Human Servs*., 956 F.2d 1144, 1147-48 (Fed. Cir. 1992).[12] The government's

[12] In *Grant*, the Federal Circuit explained the distinction between Table and non-Table claims and quoted the legislative history of the Vaccine Act as follows:

> If the petitioner sustained or had significantly aggravated an injury not listed in the Table, he or she may petition for compensation. If the petitioner sustained or had significantly aggravated an injury listed in the Table but not within the time period set forth in the Table, he or she may petition for compensation. In both these cases, however, the *petition must affirmatively demonstrate that the injury or aggravation was caused by the vaccine.* Simple similarity to conditions or time periods listed in the Table is not sufficient evidence of causation; evidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation for such a petitioner. (Such a finding of causation is deemed to exist for those injuries listed in the Table which occur within the time period set forth in the Table.)

recognition of "SIRVA" as a vaccine-caused injury was limited by the accompanying QAI criteria. In this case, I have already concluded for the reasons discussed above that petitioner has not met those criteria. Thus, if petitioner's medical theory under *Althen* prong one was limited to taking judicial notice of the government's recognition of SIRVAs as occurring in some contexts, petitioner's case would necessarily have to fail under *Althen* prong two, because the facts of petitioner's case do not fall within the confines of that recognition. *Accord L.J.,* 2021 WL 6845593 (taking judicial notice of the Table Injury of SIRVA under *Althen* prong one and applying the Table SIRVA QAI as the basis for assessing *Althen* prong two); *Tenneson*, 2018 WL 3083140 (same). To hold otherwise would be to expand the causal presumption afforded by the Vaccine Injury Table.

Here, Dr. Srikumaran opined that vaccine antigens injected into synovial tissue can cause a "prolonged immune-mediated inflammatory reaction." (Ex. 10, p. 5 (citing Atanasoff et al., *supra*, at Ex. 12.) To support this contention, Dr. Srikumaran offered several medical articles examining post-vaccination shoulder pain. In particular, the Atanasoff study found an association between vaccination and shoulder injury based on the subjects' lack of prior shoulder symptoms and rapid onset of pain following vaccination. (Atanasoff et al., *supra*, at Ex. 12, p. 8051.) The Atanasoff authors surmised that an immune-mediated inflammatory reaction induced by the vaccine caused the subjects' shoulder symptoms. (*Id.*) Given that there is no diagnostic test available to determine whether shoulder dysfunction is vaccine-caused, the Atanasoff authors emphasized the importance of evaluating clinical presentation in identifying post-vaccination shoulder injuries. (*Id.* at 8052.) Dr. Srikumaran's theory is further supported by the Bodor and Montalvo case reports that found that injection into the subdeltoid bursa likely caused "a robust local immune and inflammatory response." (Bodor & Montalvo, *supra*, at Ex. 14, p. 586.) Bodor and Montalvo concluded that "[g]iven that the subdeltoid bursa is contiguous with the subacromial bursa, [the injection] led to a subacromial bursitis, bicipital tendonitis, and inflammation of the shoulder capsule." (*Id.*)

Further to this, Dr. Srikumaran also presented the Hesse et al., study which confirms an epidemiological risk of post-vaccination bursitis. The study examined nearly three million people who received the 2016-2017 seasonal flu vaccine and looked for incidences of subdeltoid bursitis diagnosed within 180 days of vaccination. (Hesse et al., *supra*, at Ex. 21, p. 253.) The Hesse et al. authors "identified a small risk for subdeltoid bursitis with new symptom onset after injection of an influenza vaccine." (*Id.* at 259.) The Hesse et al. study specifically demonstrated bursitis as a statistically significant epidemiological finding rather than simply a clinical observation. (*See id.*)

Grant, 956 F.2d at 1147-48 (quoting H.R.Rep. No. 908, 99th Cong., 2d Sess., pt. 1, at 15 (1986), reprinted in 1988 U.S.C.C.A.N. 6344, 6356) (emphasis in *Grant*); *see also Schick-Cowell v. Sec'y of Health & Human Servs.,* 18-656V, 2022 WL 619839 (Fed. Cl. Spec. Mstr. Feb. 8, 2022); *A.P.*, 2022 WL 275785; *but see L.J.,* 2021 WL 6845593 (taking judicial notice of the Table Injury of SIRVA under *Althen* prong one for case filed prior to inclusion of SIRVA on the Vaccine Injury Table, but decided after); *Tenneson*, 2018 WL 3083140 (same).

Taken together, the literature offered by Dr. Srikumaran supports the theory that the flu vaccine can cause bursitis via post-vaccination inflammation.

In general, primary adhesive capsulitis, as opposed to secondary adhesive capsulitis, "is a specific pathologic entity in which chronic inflammation of the capsule subsynovial layer produces capsular thickening, fibrosis, and adherence of the capsule to itself and to the anatomic neck of the humerus." (Andrew Neviaser & Robert Neviaser, *Adhesive Capsulitis of the shoulder,* 19 J. AM. ACAD. ORTHROP. SURG. 536, 536 (2011) (Ex. A, Tab 9).) Thus, the SIRVA body of literature includes adhesive capsulitis among the conditions encompassed by this framework of post-vaccination shoulder injury phenomena. For example, one of the case report subjects in the above-discussed Bodor & Montalvo article suffered adhesive capsulitis. (Bodor & Montalvo, *supra,* at Ex. 14, p. 586.) Additionally, a study of the clinical characteristics of 476 SIRVA cases conceded by the government in this program showed that 5.5% of cases carried an initial diagnosis of adhesive capsulitis. (Hesse et al., *Shoulder Injury Related to Vaccine Administration (SIRVA): Petitioner claims to the National Vaccine Injury Compensation Program, 2010-2016,* 38 VACCINE 1076, 1079 (Table 4) (2020) (Ex. 20)).)

Although respondent disputes that petitioner has satisfied *Althen* prong one, I note that several petitioners in this Program have successfully relied upon on the same body of literature where the undersigned has awarded compensation in cause-in-fact shoulder claims. *E.g., Kelly v. Sec'y of Health & Human Servs.*, No. 17-1918V, 2022 WL 1144997, at *22 (Fed. Cl. Spec. Mstr. Mar. 24, 2022); *Colbert v. Sec'y of Health & Human Servs.,* No. 18-166V, 2022 WL 2232210, at *18 (Fed. Cl. Spec. Mstr. May 27, 2022); *Layne v. Sec'y of Health & Human Servs.*, No. 18-57V, 2022 WL 3225437, at *18 (Fed. Cl. Spec. Mstr. July 12, 2022).

Accordingly, petitioner has offered a reputable causal theory sufficient to meet his burden under *Althen* prong one.

ii. *Althen* prong two

The second *Althen* prong requires proof of a logical sequence of cause and effect showing that the vaccine was the reason for the injury, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu ex re. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1375–77 (Fed. Cir. 2009); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1326 (Fed. Cir. 2006); *Grant,* 956 F.2d at 1148. However, medical records and/or statements of a treating physician do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. *See* 42 U.S.C. §300aa-13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed.Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted").

Here, there is a significant issue with respect to *Althen* prong three that also prevents petitioner from demonstrating a logical sequence of cause and effect under *Althen* prong two. That issue is discussed separately below. Setting that issue aside *arguendo*, there is otherwise no question that when petitioner first sought orthopedic care, his treating orthopedist (Dr. Levin) felt he was suffering bursitis caused by an inflammatory response to vaccination. (Ex. 4, p. 9.) He later added adhesive capsulitis to his impression, which he further suggested could be related sequela. (*Id.* at 25.) This opinion accounted for two physical examinations as well as subsequent MRI findings. Moreover, Dr. Levin's stated rationale is entirely consistent with Dr. Srikumaran's theory under *Althen* prong one. However, respondent raises two issues. First, he contends that Dr. Cagle should be viewed as more persuasive in interpreting petitioner's history as consistent with a cervical spinal issue. (ECF No. 46, p. 17.) Second, he suggests that Dr. Levin's causal opinion was not definitive while petitioner's primary care provider repeatedly asserted that the vaccination had been administered properly. (*Id*. at 19.) Neither of these arguments is persuasive.

While Dr. Cagle raises some reasonable points with respect to the possibility of a cervical spinal condition being present, he is not persuasive in further suggesting that this possibility renders petitioner's diagnosed shoulder pathology unlikely. While a cervical spinal issue can sometimes be the better explanation for a clinical presentation that includes shoulder pain, the presence of cervical spinal degeneration does not preclude the presence of an additional shoulder injury. Prior petitioners have succeeded where their treating physicians diagnosed a shoulder injury in the presence of unrelated cervical spinal degeneration. *Compare Colbert v. Sec'y of Health & Human Servs.,* No. 18-166V, 2022 WL 2232210 (Fed. Cl. Spec. Mstr. May 27, 2022) *and, Layne v. Sec'y of Health & Human Servs*., 18-57V, 2022 WL 3225437 (Fed. Cl. Spec. Mstr. July 12, 2022) *with Truett v. Sec'y of Health & Hum. Servs*., No. 17-1772V, 2022 WL 17348386 (Fed. Cl. Nov. 1, 2022). Here, Dr. Srikumaran is persuasive in noting that Dr. Levin's physical examinations provided sufficient evidence to support his diagnosis of an orthopedic shoulder injury. Moreover, nothing in the medical records suggests that Dr. Levin ever felt that petitioner had a cervical condition to the exclusion of a shoulder pathology. Significant to this point is the fact that Dr. Levin continued to recommend "aggressive" therapy for adhesive capsulitis even while simultaneously recommending further investigation of petitioner's cervical spine. (Ex. 4, pp. 9, 34-35.) Thus, respondent is not persuasive in suggesting that Dr. Levin's diagnostic opinion was either tentative or rescinded following his review of the spinal MRI. Nor is the mere presence of some numbness and tingling dispositive. (Hesse et al., *supra,* at Ex. 20, p. 1080 (Table 4) (indicating that 7.4% of conceded SIRVAs included tingling or paresthesia).)

Nor is Dr. Oh's skepticism that petitioner's injury could have been vaccine-related controlling. The only reason Dr. Oh indicated for skepticism is the assertion that petitioner's vaccine was correctly administered. (Ex. 3, p. 7.) However, that does not preclude a SIRVA. Petitioner has filed a study by Hesse, et al., evaluating the clinical characteristics of conceded SIRVA claims within this program. According to that paper, less than half of SIRVA cases include any alleged error in vaccine administration.

(Hesse et al., *supra,* at Ex. 20, p. 1080.) Moreover, the literature cited by Dr. Cagle also suggests that, to the extent overpenetration is suspected as a contributing factor in SIRVA, needle penetration into the bursa may be attributable to needle length and anatomical diversity without the need for improper technique, explaining

> Current Centers for Disease Control and Prevention guidelines state that a 1-inch needle depth is appropriate for most patients (except for persons >200 lbs or new-borns), which is a seemingly "one-size-fits-all" approach for an increasingly diverse population. A study of MRI deltoid fat pads by Lippert found that with using 5/8 inch, 7/8-inch, or 1/inch needles for intramuscular deltoid injections would cause 11% (16 of 150), 55% (83 of 150), and 61% (92 of 150) of patients to experience overpenetration, respectively.

(Matthew Barnes et al., *A "Needling" Problem: Shoulder Injury Related to Vaccine Administration,* 25(9) J. AM. BOARD FAM. MED. 919, 921 (2012) (Ex. A, Tab 2).) The authors characterize the argument for changing vaccination technique as "compelling." (*Id.*) According to these authors, based on the 160 lbs documented during petitioner's October 8, 2016 encounter, petitioner would have to have had his vaccination administered with a needle shorter than what the CDC typically recommends in order to ensure there was no overpenetration. (*Id.*; *see* Ex. 3, p. 18.) Thus, it is not necessary for petitioner to demonstrate any incorrect injection technique in order to demonstrate a logical sequence of cause and effect between his vaccination and his injury.

Accordingly, if not for the timing of onset that is fatal to petitioner's claim, petitioner's medical records coupled with Dr. Srikumaran's additional supporting opinion would otherwise preponderantly establish a logical sequence of cause and effect between petitioner's vaccination and his alleged shoulder injury.

iii. *Althen* prong three

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). In this case, Dr. Srikumaran is unpersuasive in suggesting that the medically acceptable timeframe during which vaccine causation of a shoulder injury can be inferred extends as far as two months post-vaccination. (Ex. 10, p. 5; Ex. 18, p. 5.) He is further unpersuasive in suggesting that the one-week post-vaccination onset present in this case supports any inference of causation.

The two-month timeframe referenced by Dr. Srikumaran is derived from two outlier case reports in a study by Arias, et al., of prior reported cases of potential SIRVA. The Arias authors undertook a review of 67 prior medical articles and 13,717 reports of vaccine-related notifications from the Adverse Reaction Data of the Spanish

Pharmacovigilance System or "FEDRA" to assemble a case series of 45 subjects. (Martin Arias et al., *supra,* at Ex. 13.) The authors assessed 37 cases from the published literature and 8 cases from FEDRA. Among the published cases, post-vaccination onset ranged from immediate to three days. (*Id*. at 3 (Table 2).) Among the FEDRA cases, 6 of the 8 were noted to have had onset occurring within 7 days of vaccination. Out of all the cases reviewed by Arias, et al., only two cases from FEDRA had latencies beyond one-week post-vaccination and only one case had a latency of one week. (*Id.* at 3.) Moreover, nothing in the authors' analysis specifically endorses a view that the cases involving longer latencies were vaccine-caused. Instead, the authors conclude that 48 hours is the likely relevant onset based on the majority of cases falling within that timeframe. (*Id*. at 1 (abstract).)

In contrast, a statistical analysis also cited by Dr. Srikumaran examined cases of bursitis occurring within 180 days of vaccination and used the 60 days post-vaccination period as the background rate to find a statistically elevated risk of bursitis occurring within 3 days post-vaccination. (Hesse et al., *supra,* at Ex. 21.) Indeed, the literature as a whole suggests that a clear majority of vaccine-related shoulder injuries occur within 48 hours of vaccination with some anecdotal evidence potentially supporting that onset may occur a few days later in a minority of cases. (*See* Atanasoff, et al., *supra,* at Ex. 12, p. 8050 (one out of 13 cases occurred 4 days post-vaccination; Martin Arias et al., *supra,* at Ex. 13, p. 4872 (noting "6 in 8 FEDRA patients complained of increasing severity pain starting within the first 24 h or few days (4-7 days) post-vaccination."); Hesse et al., *supra,* at Ex. 21, p. 253 (statistically significant elevated risk of bursitis in the first three days post-vaccination).

Nor does the experimental evidence Dr. Srikumaran cites persuasively address the issue. While Trollmo, et al., sought to compare intra-articular injections to subcutaneous injections, it is not clear how those findings regarding systemic immune response would support the timing of onset in this case. (Trollmo et al., *supra,* at Ex. 17.) Regardless of the measurements taken, all six of the subjects receiving intra-articular injections experienced temporary swelling and stiffness of the injected joint within two to four hours of vaccination. (*Id.* at 386.) Dumonde & Glynn is a study involving a rabbit model designed to examine rheumatoid arthritis. (Dumonde & Glynn, *supra,* at Ex. 15.) On this record, Dr. Srikumaran has not substantiated its relevance on the specific issue of timing of onset. While the study examined changes within injected joints over a period of weeks, it was not equipped to detect the onset of pain symptoms.

Dr. Cagle was also somewhat unpersuasive in that he urged "the accepted 48 hour standard" without further explanation. (Ex. A, p. 6.) An issue that is evident in the body of SIRVA literature is that some of the larger studies treat the 48-hour onset as a threshold screening issue. For example, the 2019 study by Hesse, et al., examines 476 cases of SIRVA that were conceded within this program. (Hesse et al., *supra,* at Ex. 20, p. 1076.) This provides valuable insight regarding variation in clinical characteristics among confirmed SIRVAs, but does not provide evidence regarding the full scope of what might reasonably constitute a SIRVA-like injury caused-in-fact by vaccination, because it is limited to cases conceded by the government and those concessions are

governed by the QAI criteria now included on the Vaccine Injury Table, including the requirement of a 48 hour onset. Similarly, a study by Hibbs, et al., examined reports of shoulder injuries reported to the Vaccine Adverse Event Reporting System (VAERS), but only considered reports with onset occurring within 48 hours of vaccination. (Beth F. Hibbs et al., *reports of atypical shoulder pain and dysfunction following inactivated influenza vaccine, Vaccine Adverse Event Reporting System (VAERS), 2010-2017,* 38 VACCINE 1137 (2020) (Ex. 22).) Yet, strict adherence to a 48-hour onset as utilized by these studies is refuted by the Hesse, et al., study, which found a statistically significant elevation of risk for three days post-vaccination. (Hesse et al., *supra,* at Ex. 21.) In that regard, the Federal Circuit holding in *Paluck v. Secretary of Health & Human Services* cautions against setting "hard and fast deadline[s]" for onset. *See* 786 F.3d 1373, 1383-84 (Fed. Cir. 2015) (stating that "[t]he special master further erred in setting a hard and fast deadline" for onset and noting that the medical literature filed in the case "do not purport to establish any definitive timeframe for onset of clinical symptoms."). Nonetheless, petitioner bears the burden of proof on this point and, even without treating the 48-hour period as a bright line, there is little to no evidence on this record to specifically support a one-week latency as medically reasonable.

Balancing all of the above, I conclude on this record that petitioner has not satisfied *Althen* prong three based on a one-week post-vaccination onset. This is consistent with prior cases which have generally fallen into two categories. Several prior cases have denied entitlement to compensation where onset of shoulder pain occurred months post-vaccination. *Nicholson v. Sec'y of Health & Human Servs.,* No. 17-1416V, 2022 WL 14437541, at *25-26 (Fed. Cl. Spec. Mstr. Sept. 22, 2022) (denying entitlement where onset of shoulder pain occurred between 32-49 days post-vaccination); *Clavio v. Sec'y of Health & Human Servs*., No. 17-1179V, 2022 WL 1078175, at *8 (Fed. Cl. Spec. Mstr. Feb. 16, 2022) (denying entitlement where onset of shoulder pain was 59 days post-vaccination); *Mack v. Sec'y of Health & Human Servs*., No. 15-0149V, 2016 WL 5746367, at * 10-11 (Fed. Cl. Spec. Mstr. July 14, 2016) (explaining that the 48-hour onset required by the Vaccine Injury Table does not preclude "a claim involving a later onset (even one that is substantially later)" but finding petitioner failed to demonstrate a six-month post-vaccination onset is medically reasonable to infer causation). On the other hand, several prior cases have suggested that onset falling outside of the 48-hour Table window but within less than one week post-vaccination can support a cause-in-fact shoulder injury claim. *Kuczarski v. Sec'y of Health & Human Servs*., No. 20-0312V, 2023 WL 1777208, at *3-4 (Fed. Cl. Spec. Mstr. Feb. 6, 2023) (dismissing Table SIRVA claim but noting that "a causation-in-fact injury claim might still be tenable, based on an onset occurring a week after vaccination."); *Murray v. Sec'y of Health & Human Servs*., No. 17-1357V, 2022 WL 17829797 (Fed. Cl. Spec. MStr. Oct. 27, 2022) (finding entitlement where onset of shoulder pain occurred within "a few days" and less than seven days post-vaccination); *Jewell v. Sec'y of Health & Human Servs*., No. 16-0670V, 2017 WL 7259139, at * 3 (Fed. Cl. Spec. Mstr. Aug. 4, 2017) (finding entitlement for shoulder injury occurring 72 hours post-vaccination); *but see C.C. v. Sec'y of Health & Human Servs.,* No. 17-708V, 2021 WL 2182817 (Fed. Cl. Spec. Mstr. Mar. 31, 2021) (finding onset of shoulder pain one-week post-vaccination did not satisfy *Althen* prong three because petitioner's *Althen* prong

one theory was based on the Vaccine Injury Table, which required a 48-hour onset); *Porcello v. Sec'y of Health & Human Servs.*, No. 17-1255V, 2020 WL 4725507, at *9 (Fed. Cl. Spec. Mstr. June 22, 2020) (denying entitlement where petitioner failed to show onset "reasonably close" in time to vaccination where the only precise notation of onset indicated an 11-day latency).

VI. Conclusion

Petitioner has my sympathy for what he has endured. However, considering the record as a whole under the standards applicable in this Program, petitioner has not preponderantly established either that his October 8, 2016 flu vaccination resulted in a Table SIRVA or alternatively caused-in-fact a shoulder injury. Accordingly, petitioner is not entitled to compensation. Therefore, this case is dismissed.[13]

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master

[13] In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.